ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-03-15339	89110000503	9/14/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334179

RECEIVED
OPPT CBIC
2011 SEP 14 AM 11:49

Andrea V. Malinowski
Corporate Counsel

DuPont Legal
Wilmington Office Buildings D-7078
1007 Market Street
Wilmington, DE 19898
302-774-6443 Tel 302-774-1189 Fax
andrea.v.malinowski@usa.dupont.com E-mail

September 13, 2011

VIA FEDERAL EXPRESS

Attn: TSCA Declassification Coordinator
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC)
EPA East Building, Room 6428
1201 Constitution Avenue
Washington, D.C. 20004-3302

Public Copy

Re: Declassification Activity - TSCA §8(e) Submission
Originally Assigned 8EHQ Number: 8EHQ-03-15339 (letter dated 05.15.03)
Originally Assigned Bar Code: 88030000134
Supplemental Submission - Revised Public Copy of Submission

Dear TSCA Declassification Coordinator:

The above-identified TSCA §8(e) submission was reviewed in connection with the EPA 2010 CBI Declassification Challenge initiative. For that submission only, it was determined that the confidential business information (CBI) claims may be withdrawn.

Please find enclosed a revised public copy of the above-identified submission. The originally assigned 8EHQ number has been added by the submitter to the first page of the enclosed revised public copy of the submission. Please note that by withdrawal of the CBI claims, DuPont is not relinquishing any property rights to the study in issue.

Very truly yours,

Andrea V. Malinowski (dwd)

Andrea V. Malinowski

Enclosure

CONTAINS NO CBI

Revised Public Copy - Submitted 09.13.11
Originally Assigned 8EHQ Number: 8EHQ-03-15339
Originally Assigned Bar Code: 88030000134

PUBLIC COPY

DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

May 15, 2003

Via Federal Express

~~CONFIDENTIAL BUSINESS INFORMATION~~

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20460

Dear 8(e) Coordinator:

Phosphonium, tetrabutyl-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-1-butanesulfonic acid (1:1)
CAS Registry Number 220689-12-3
Generic Name: Phosphonium salt of substituted alkylsulfonate

This letter is to inform you of the results of a recently conducted four-week study in rats with a four-week recovery period with the above referenced test material. This study was sponsored by General Electric Company and DuPont, and this letter is being provided on behalf of both companies.

Groups of male and female rats (13/sex/dose) were administered 0, 5, 50, or 200 mg/kg/day of the test material by oral gavage. Body weight, food consumption, detailed clinical observations, neurobehavioral and clinical pathology parameters were evaluated in all rats. Eight rats/sex/dose were sacrificed and necropsied at the end of the dosing period. Microscopic evaluation was conducted on all tissues from control and high-dose rats and on nasal tissue from low- and intermediate-dose rats. The remaining 5 rats/sex/dose were held without dosing for a four-week recovery period. Microscopic evaluation was conducted on nasal tissue from all recovery group rats.

No adverse test material-related effects were observed on any body weight, nutritional, neurobehavioral, or clinical pathology parameters in any dose group. Minimal to moderate focal degeneration/regeneration of the olfactory epithelium of the nose was present in male and female rats dosed with 50 mg/kg/day and above at the end of the dosing period. The incidence of this lesion was 5/8 and 4/8 in males and females, respectively, dosed with 200 mg/kg/day, and 4/8 and 3/8 in males and females, respectively, dosed with 50 mg/kg/day. At the end of recovery, a few intraepithelial cysts were observed in 4/5 and 3/5 male and female rats, respectively, in the 200 mg/kg/day group, and in 3/5 and 1/5 male and female rats, respectively, in the 50 mg/kg/day group. These cysts were considered to accompany late-stage regrowth of the olfactory epithelium, indicating recovery was almost completed. No similar effects were observed at the end of the dosing or recovery periods in male or female rats dosed with 5 mg/kg/day.

The nasal lesions observed in this study were generally of a mild nature and do not represent a unique lesion, as similar lesions have been observed in other rat oral gavage studies. Consistent with the known regenerative capacity of olfactory epithelial tissue, the architecture was re-established by the end of the recovery period in the dose groups affected. Although olfactory lesions were seen in rats dosed with the two highest levels, a clear no-adverse effect level was established.

Under these experimental conditions, the pathological changes described above appear to be reportable, based upon EPA guidance given in the EPA TSCA Section 8(e) Reporting Guide (June, 1991).

~~Substantiation of our confidentiality claim is enclosed.~~

Sincerely,

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs and Occupational Health

AMK/JCS/SAM:clp
(302) 366-5260

cc: Dean Branson, Ph.D.
Product Stewardship Manager
General Electric Company
1 Lexan Lane
Mt. Vernon, IN 47620

From: (302) 773-0071
Doris Duffy
E I. du Pont de Nemours & Co.
1007 Market Street
D-7096-1
Wilmington, DE 19898

Ongin ID: ZWIA

FedEx Express

J11201104290225

Ship Date: 13SEP11
ActWgt: 1.0 LB
CAD: 4554543/INET3180

Delivery Address Bar Code

SHIP TO: (202) 564-8955 BILL SENDER

Confidential Bus Info (CBIC)
US EPA Off of Poll Prevent & Toxics
EPA East Building, Room 6428
1201 Constitution Avenue
Washington, DC 20004

Ref #
Invoice #
PO #
Dept #

WED - 14 SEP A1
PRIORITY OVERNIGHT

TRK# 7951 7905 6400
0201

ZD RDVA

20004
DC-US
DCA

50FG2/4299/F5F4